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*JPW*

PTO/SB/21 (09-04)

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## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/694,664
Filing Date	10/29/2003
First Named Inventor	Gartner, William
Art Unit	
Examiner Name	
Attorney Docket Number	04878_01/0201

### ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input checked="" type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers  <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Request for Refund  <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC  <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences  <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)  <input type="checkbox"/> Proprietary Information  <input type="checkbox"/> Status Letter  <input type="checkbox"/> Other Enclosure(s) (please identify below):
<div>Remarks</div> <p>Affidavit of William Gartner Affidavit of Steven Feyrer-Melk</p>		

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Chambliss, Bahner & Stophel, P.C.		
Signature	<i>Paul S. Weidlich</i>		
Printed name	Paul S. Weidlich		
Date	May 27, 2005	Reg. No.	43980

### CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	<i>Paul S. Weidlich</i>		
Typed or printed name	Paul S. Weidlich	Date	May 27, 2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

In re Application of: Gartner, William )  
Title: Self-Scoring Method and )  
Apparatus for Early Self- ) Examiner: Suhol, Dmitry  
Screening of Neurological )  
Disease ) Art Unit: 3712  
Serial No.: 10/015,442 )  
Date: 12/13/2001 )

**AFFIDAVIT OF STEVEN FEYRER-MELK**  
**UNDER 37 C.F.R. § 1.131**

I, Steven Feyrer-Melk, of full age, do hereby attest as follows:

1. I am a co-inventor of the invention claimed in the application referenced above (the "Application"). As such, I am fully familiar with the facts set forth below.
2. William Gartner, the other co-inventor of the invention claimed in the Application, and I conceived the invention claimed in the Application before April 2, 2001, the filing date of U.S. Publication No. 2002/0139170A1 of Doty ("Doty").
3. A description of the apparatus and method of the invention is documented under the heading "Instructions for Early Alert™ Alzheimer's Home Screening Test," which is attached hereto as Exhibit A. As the Instructions expressly provide, the apparatus of the invention comprises a booklet, a plurality of pages, a plurality of smell labels, instructions for scoring, a structure whereby an answer may be circled, an answer key, and instructions for interpreting the score achieved. In addition, the Instructions describe the steps of the method of the invention, including providing an odor-containing source capable of releasing an odor (2), providing a plurality of choices of possible identity of the odor-containing source (3 and 4), providing an answer key (6), and providing an instruction for self-scoring (6, 7 and footnote \*). The

document attached as Exhibit A is a copy of the original which was created on February 4, 2001, nearly two (2) months prior to the filing date of Doty.

4. An example of the plurality of labels from which a user of the invention may select an answer is provided in the document attached hereto as Exhibit B. The document attached hereto as Exhibit B is a copy of the original which was created on January 10, 2001, nearly three (3) months prior to the filing date of Doty.

5. An example of an answer key according to the invention claimed in the Application is provided in the document attached hereto as Exhibit C. The document attached hereto as Exhibit C is a copy of the original which was created on February 4, 2001, nearly two (2) months prior to the filing date of Doty.

6. Additional instructions regarding self-scoring according to the invention claimed in the Application is provided in the document attached hereto as Exhibit D. The document attached hereto as Exhibit D is a copy of the original which was created on January 21, 2001, more than two (2) months before the filing date of Doty.

7. Additional evidence of the conception of the invention claimed in the Application is provided by the product packaging, which is attached hereto as Exhibit E. The document attached hereto as Exhibit E is a copy of the original which was created on December 29, 2000, more than three (3) months prior to the filing date of Doty.

8. Additional evidence of the conception of the invention claimed in the Application is provided by the "Information About Olfactory Function and Alzheimer's Disease," which is attached hereto as Exhibit F. The document attached hereto as Exhibit F is a copy of the original which was created on February 4, 2001, nearly two (2) months prior to the filing date of Doty.

9. Additional evidence of the conception of the invention claimed in the Application is provided by the summary outline entitled "Alzheimer's Meeting (SAFM Home Office) Will Gartner and Steven Feyrer-Melk," which is attached hereto as Exhibit G. The document attached hereto as Exhibit G is a copy of the original which was created on November 20, 2000, more than four (4) months prior to the filing date of Doty.

10. Each of the documents attached hereto as Exhibits A through G were created in the United States of America. Further, the invention was completed in the United States of America prior to April 2, 2001, the filing date of Doty. In addition, Doty has not resulted in an issued patent. Consequently, the issue date of Doty is not more than one (1) year prior to the filing date of the Application, December 13, 2001. In fact, the filing date of the Application precedes the publication date of Doty, October 3, 2002, by nearly one (1) year.

11. The co-inventors of the invention claimed in the Application exercised due diligence from prior to the filing date of Doty until the filing date of the Application. More particularly, the co-inventors of the invention claimed in the Application exercised due diligence from April 1, 2001 until December 13, 2001. By way of illustration, between April 1, 2001 and December 13, 2001, the co-inventors engaged in the following activities:

- worked through quality control issues concerning the manufacture of the test smell strips (See Exhibit H);
- analyzed and modified the scoring sensitivity and specificity of the smell test (See Exhibit I);
- pursued and obtained a trademark for the mark Early Alert® (See Exhibit J);
- developed an Early Alert® product carton (See Exhibit K);
- developed an Early Alert® product box (See Exhibit L);

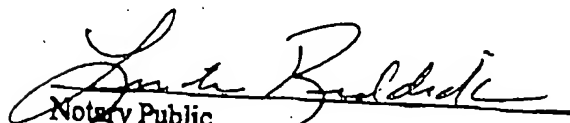
- negotiated royalty rates and licensing agreements for the product (See Exhibit M); and
- assisted patent counsel in the preparation of the Application that was ultimately filed on December 13, 2001 (See Exhibit N).

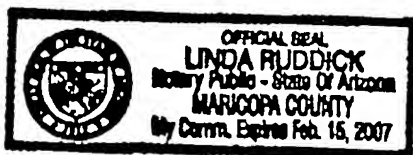
12. I submit this Affidavit under 37 C.F.R. 1.131 in support of the removal of Doty as a valid prior art reference against the Application.

13. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

  
Steven Feyrer-Merk, co-inventor

Sworn to and subscribed before me  
this 13 day of May, 2003.

  
Notary Public  
My Commission Expires: Feb 15, 2007



1. This odor smells  
most like

- a. gasoline
- b. pizza
- c. peanuts
- d. lilac

4. This odor smells  
most like

- a. dill pickle
- b. bubble gum
- c. wintergreen
- d. watermelon

7. This odor smells  
most like

- a. tomato
- b. licorice
- c. strawberry
- d. menthol

10. This odor smells  
most like

- a. whiskey
- b. honey
- c. lime
- d. cherry

2. This odor smells  
most like

- a. gasoline
- b. pizza
- c. peanuts
- d. lilac

5. This odor smells  
most like

- a. dill pickle
- b. bubble gum
- c. wintergreen
- d. watermelon

8. This odor smells  
most like

- a. tomato
- b. licorice
- c. strawberry
- d. menthol

11. This odor smells  
most like

- a. whiskey
- b. honey
- c. lime
- d. cherry

3. This odor smells  
most like

- a. gasoline
- b. pizza
- c. peanuts
- d. lilac

6. This odor smells  
most like

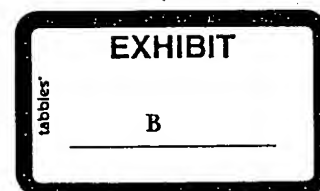
- a. dill pickle
- b. bubble gum
- c. wintergreen
- d. watermelon

9. This odor smells  
most like

- a. tomato
- b. licorice
- c. strawberry
- d. menthol

12. This odor smells  
most like

- a. whiskey
- b. honey
- c. lime
- d. cherry



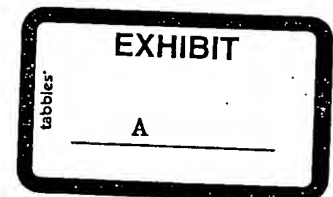
oil 10/10/11



## INSTRUCTIONS FOR EARLY ALERT™ ALZHEIMER'S HOME SCREENING TEST\*

1. DO NOT ATTEMPT THE TEST IF YOU CURRENTLY HAVE NASAL CONGESTION OR LONG-STANDING SMELL LOSS DUE TO HEAD TRAUMA OR OTHER KNOWN CAUSES
2. GO TO THE FIRST PAGE OF THE TEST (SMELL #1) AND SCRATCH THE COLORED SMELL LABEL WITH A PENCIL FROM LEFT TO RIGHT SEVERAL TIMES IN A ZIG-ZAG FASHION TO RELEASE THE ODOR. THEN PLACE THE LABEL OVER BOTH NOSTRILS AND SNIFF IT.
3. CIRCLE THE BEST ANSWER; IF NOT SURE OR NO SMELL IS PRESENT, TRY TO GUESS ANYWAY
4. CONTINUE UNTIL ALL 12 SMELL LABELS HAVE BEEN SNIFFED AND AN ANSWER HAS BEEN CIRCLED FOR EACH
6. AFTER COMPLETION OF THE TEST, TURN TO THE ANSWER KEY ON THE LAST PAGE OF THE BOOK AND DETERMINE YOUR TEST SCORE (I.E., HOW MANY OF THE 12 ITEMS YOU MISSED)
7. IF YOU MISSED MORE THAN TWO ITEMS, YOU SHOULD CONTACT YOUR PHYSICIAN FOR FURTHER EVALUATION

\*See last page of the test booklet for further information concerning the interpretation of the results.



1012

Created on 2/04/01



**EARLY ALERT™ SCORING KEY (CORRECT ANSWERS)**

ODOR #1 - B. CINNAMON

ODOR #2 - A. TURPENTINE

ODOR #3 - D. LEMON

ODOR #4 - C. SMOKE

ODOR #5 - B. CHOCOLATE

ODOR #6 - B. ROSE

ODOR #7 -- D. PAINT THINNER

ODOR #8 -- A. BANANA

ODOR #9 - C. PINEAPPLE

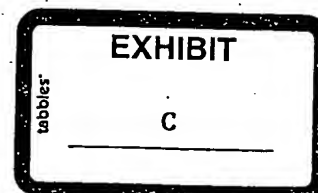
ODOR #10 - D. GASOLINE

ODOR #11 - A. SOAP

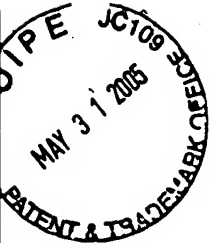
ODOR #12 - C. ONION

1012

Created on 2/04/01

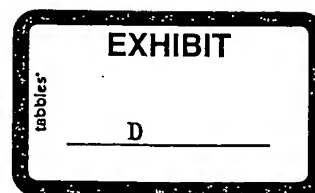




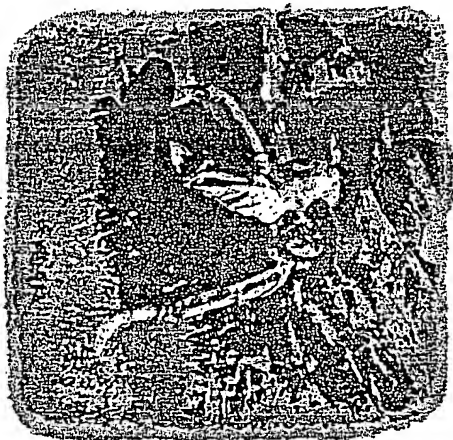


Please Note: (Disclaimer)

1. Early Alert Alzheimer's Home Screening has been designed to assist in early detection of possible Alzheimer's disease. False positives are possible with this test.
2. Failing the Early Alert Alzheimer's Home Screening does not mean you have Alzheimer's disease. Early Alert Alzheimer's Home Screening is NOT a diagnostic test nor a conclusive test for Alzheimer's disease. You must follow up by seeing a physician.
3. If you have any reason to believe you may have Alzheimer's Disease, see a doctor.



created on 01/21/01



Did you ever Wonder?

- Memory loss affecting job skills?
- Difficulty performing familiar tasks?
- Misplacing things?

[www.AlzheimersTestKit.com](http://www.AlzheimersTestKit.com)  
1-800-123-4567

**19 MILLION AMERICANS**  
say they have a family member  
with Alzheimer's disease.

**EARLY ALERT**  
**Alzheimer's**  
**Home Screening**  
**Test**  
**SIMPLE • FAST**  
**NON-INVASIVE**

# Alzheimer's Disease Screening

**EARLY ALERT**

**Alzheimer's Home Screening**

[www.AlzheimersTestKit.com](http://www.AlzheimersTestKit.com)

**SIMPLE • FAST • NON-INVASIVE**

**DISCLAIMER:**

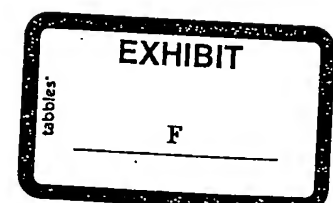
1. Early Alert Alzheimer's Home Screening is not a conclusive test for Alzheimer's Disease.
2. False positives are possible with this test.
3. Early Alert Alzheimer's Home Screening has been designed to assist in early detection of Possible Alzheimer's Disease.

4. Only a full Alzheimer's Home Screening is NOT an Alzheimer's Disease diagnostic test and you MUST follow up by seeing a physician.
5. Failing the Early Alert Alzheimer's Home Screening does not mean you have Alzheimer's Disease.
6. If you have any reason to believe you may have Alzheimer's Disease, see a doctor.

## INFORMATION ABOUT OLFACTORY FUNCTION AND ALZHEIMER'S DISEASE

Smell loss is among the first signs of Alzheimer's disease (AD). Although not all older persons with smell loss have AD, such loss -- alone or in combination with memory problems and/or certain genetic markers -- is among the best predictors or indicators of AD. Early Alert™ has been designed to assist in early detection of possible Alzheimer's disease. However, false positives and false negatives are possible with this test. Failing this test does not mean you have Alzheimer's disease. Early Alert™ is NOT a diagnostic test nor a conclusive test for Alzheimer's disease. Nonetheless, poor performance on this test should be followed up by evaluation by a physician. Medical and scientific studies on smell function and AD include:

Bacon et al. (1998) Very early changes in olfactory functioning due to Alzheimer's disease and the role of apolipoprotein E in olfaction. *Ann NY Acad Sci* 855, 723-751; Devanand DP et al (2000) Olfactory deficits in patients with mild cognitive impairment predict Alzheimer's disease at follow-up. *Amer J Psychiat* 157, 1399-1405; Doty RL et al (1987) Presence of both odor identification and detection deficits in Alzheimer's disease. *Brain Res Bull* 18, 597-600; Doty et al. (1991) Olfactory dysfunction in three neurodegenerative diseases. *Geriatrics* 46 (Suppl 1), 47-51; Graves AB et al. (1999) Impaired olfaction as a marker for cognitive decline: interaction with apolipoprotein E epsilon4 status. *Neurology* 53, 1480-1487; McCaffrey RJ et al. (2000) Olfactory dysfunction discriminates probable Alzheimer's dementia from major depression: A cross validation and extension. *J Neuropsychiat Clin Neurosci* 12, 29-33; Murphy C et al (1998) Apolipoprotein E status is associated with odor identification deficits in nondemented older persons. *Ann NY Acad Sci* 855, 744-750; Serby M et al (1991) The nature and course of olfactory deficits in Alzheimer's disease. *Amer J Psychiat* 148, 357-360; Serby et al (1996) Olfactory identification deficits in relatives of Alzheimer's disease patients. *Biol Psychiat* 39, 375-377; Solomon GS et al (1998) Olfactory dysfunction discriminates probable Alzheimer's dementia from major depression. *J Neuropsychiat Clin Neurosci* 10, 64-67.



11/20/00

**Alzheimer's Meeting (SAFM Home Office)  
Will Gartner & Steven Feyrer-Melk**

Discussed AD test

Discussed conversation with Dr. Doty from Sonsonics

Discussed next steps for product

Letter to Doty

We provide material they deposit smell

Quote

100

Can they be sealed in plastic shrink wrap

Susan will write disclaimer

Needs sample tests

Needs research

Discussed Test

Miss 2 or more contact a physician

Discussed Format of test

2 fold

Front Cover with name

Inside cover directions (why test smell)

Bottom inside smells with blanks

Back waiver/disclaimer and answers behind tape

Buy sample tests

Discussed list of "things to do"

Disclaimers

See Medical Attorney

Develop prototype

Website Development

Packaging

Trip to Sonsonics

Advertisement (AARP, Suncity cities, papers)

Think of Names

Early Alert

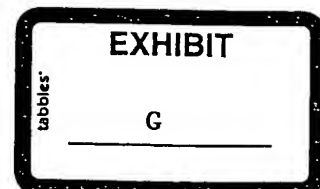
Early Alert Alzheimer's Test

Alzheimer's Home Screening Test

Discussed pricing

(Use Alzheimer's fact sheet, statement of science behind the test)

Question: What if someone takes the test and does harm to themselves? Could be psychologically powerful.



11/20/00

**Subj: Re: Shipments received**  
**Date: 5/21/01 2:27:17 PM US Mountain Standard Time**  
**From: doty@mail.med.upenn.edu (Richard L. Doty Ph.D.)**  
**To: WilGartner@aol.com**

Dear Will:

Thanks for the feedback regarding the tests; I will implement a closer quality control on the production and will review what gets sent out. I have talked to the company who is manufacturing the tests and will also review the remaining tests to be sent out.

Sorry for these problems. I'm responding to your other e-mail now.

Dick

At 02:04 AM 5/21/2001 EDT, you wrote:

>Dick:

>

>WE received a shipment on Saturday of 200 Test Kits that have the Sensonics  
>Smell STRips (all brown). Of the 200 4 were rejected because three were  
>missing one smell strips and one had an improperly placed smell strip.

>

>We received a shipment of 225 Test Kits on Sunday that have the new Smell  
>Of these, 76 were

>rejected for one or more of the following reasons:

>

>Missing a smell strip (~3 kits)

>

> (~5 kits)

>

>No white out tape (~190 kits)

>

>smell strip very crooked (~40)

>

>Outside back cover is blurry (~4 kits)

>

>Incorrect smell strip pulled off, tearing or peeling the paper, and a new  
>smell strip put in its place.(~6)

>

>We need to discuss the implementation of stronger quality control measures.

>While we went through all 400 test kits, we don't relish the idea of going  
>through 10,000 let alone 68,000 when we get the Walgreens order.

>

>May we please have your thoughts on these issues in a phone conversation  
>Monday afternoon between 1 and 3 PM PHX time.

>

>Thanks for getting the kits to us for the Walgreens presentation. We will  
use

>the colored smell strips units for that.

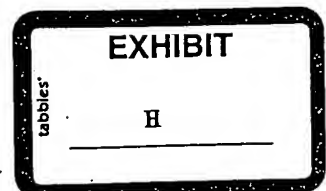
>

>Thanks,

>

>Will

>



Subj: **BIG PROBLEM**  
 Date: 5/10/01 10:11:29 PM US Mountain Standard Time  
 From: safm.phd@home.com (Steven A. Feyrer-Melk, Ph.D.)  
 To: WilGartner@aol.com (WilGartner@aol.com)

Will,

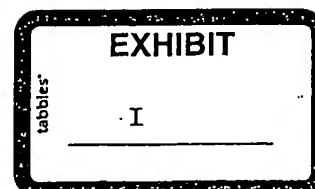
We need to TALK! This is a problem.

Return-Path: <doty@mail.med.upenn.edu>  
 Received: from mh6-tx.mail.home.com ([65.10.73.148])  
 by mail1.rdc1.az.home.com  
 (InterMail vM.4.01.03.20 201-229-121-120-20010223) with ESMTP  
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 for <safm.phd@mail.phnx1.az.home.com>;  
 Thu, 10 May 2001 21:31:28 -0700  
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 by mh6-tx.mail.home.com (8.9.3/8.9.0) with ESMTP id VAA10047  
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 by mx6-tx.mail.home.com (8.11.1/8.11.1) with ESMTP id f4B4VRR22248  
 for <safm.phd@home.com>; Thu, 10 May 2001 21:31:27 -0700 (PDT)  
 Received: from doty (node.uphs.upenn.edu [165.123.243.13])  
 by dolphin.upenn.edu (8.11.1/8.10.1) with SMTP id f4B4VQ108376;  
 Fri, 11 May 2001 00:31:26 -0400 (EDT)  
 Message-Id: <3.0.6.32.20010511003143.00ac7ac0@mail.med.upenn.edu>  
 X-Sender: doty@mail.med.upenn.edu  
 X-Mailer: QUALCOMM Windows Eudora Light Version 3.0.6 (32)  
 Date: Fri, 11 May 2001 00:31:43 -0400  
 To: sfm@FMGinnovations.com, safm.phd@home.com  
 From: "Richard L. Doty Ph.D." <doty@mail.med.upenn.edu>  
 Subject: cut off for concern on test  
 Mime-Version: 1.0  
 Content-Type: text/plain; charset="us-ascii"  
 X-Mozilla-Status2: 00000000

Steve -- I have gone back and looked carefully at the cut-off score we proposed for the test. A cut-off of 3 (i.e., a score of 9) I believe is somewhat too liberal. While being high on sensitivity, it would be quite low on specificity and would lead to far too many false positives.

Looking at the norms for the 12-item test and going back to my 1987 AD paper, I think we need to have as the criterion for seeing a physician a somewhat different number. Here is my reasoning.

In the 1987 paper and elsewhere, the average UPSIT score for AD patients is around  $20/40 = 50\%$  of the total score. Therefore, the average B-SIT score for an AD patient would be 50% of 12 or about 6 wrong. In determining an upper range, if we look at the range of scores in the AD patients, and look at the upper few scores and accept a small degree of overlap, they are around 28/40 or so on the UPSIT (62.5%). Hence, the highest score where we would start being concerned about AD on the B-SIT would be 62.5% of 12 or 7.5; hence,  $12 - 7.5 = 4.5$  wrong. Thus, a cut-off of 5 would probably be a better indicator than a cut-off of 3.



This has considerable ramifications. Looking at the percentiles in the 1996 Laryngoscope paper, the following would apply using 3 wrong (9 right) as the cutoff for the older age groups:

Age:	60-64,	65-69,	70-74,	75-79,	80-84,	and >84 yrs
Male %ile:	21	34	45	43	71	77
Female %ile:	10	14	34	48	64	69

If we accept, however, a cut off of 5 wrong (7 right), there corresponding percentile figures would be as follows:

Age:	60-64,	65-69,	70-74,	75-79,	80-84,	and >84 yrs
Male %ile:	12	19	23	28	48	56
Female %ile:	04	03	10	25	40	40

If you compare the number of subjects who would seek medical help, the percentage differences between the two groups would be as follows (the numbers represent the percentage more who would be seeking help under the current criteria of 3 wrong):

Age:	60-64,	65-69,	70-74,	75-79,	80-84,	and >84 yrs
Male %:	9%	15%	22%	15%	23%	21%
Female %:	6%	11%	24%	23%	24%	29%

These numbers are considerable. For example, if one accepts the notion that the percentages largely reflect a false positive rate, in most of the older age categories we decrease the false positive rate by over 20% by changing the criterion to 5 rather than 3 wrong. While one could argue that it is better to have a false positive than a false negative, the specificity of the test becomes suspect.

My feeling is that we should change the criteria from 3 to 5 at this point, even if we have to put little labels over the first batch of tests to minimize criticism and a statistical criticism of the testing. Alternatively, this could all be explained in the inserts and a simple explanation of what I present above presented.

Your thoughts are appreciated. I am responding to some of the comments of critics that missing three items may not be so difficult. This forced me to re-examine the original assumptions, and I think it would be prudent to change the criterion or provide alternative criteria in the instruction set.

Dick

Richard L. Doty, Ph.D.  
 Professor & Director  
 Smell & Taste Center  
 University of Pennsylvania Medical Center  
 5 Ravdin Building  
 3400 Spruce Street  
 Philadelphia, PA 19104  
 Phone: 215-662-6580  
 FAX: 215-349-5266  
 e-mail: doty@mail.med.upenn.edu

----- Headers -----  
 Return-Path: <safrn.phd@home.com>

Friday, May 11, 2001 America Online: WilGartner

willgartner@qwest.net

From: "Trademark Electronic Application System TEAS service" <PrinTEAS@uspto.gov>  
To: <wjg@FMGinnovations.com>  
Cc: <teas@uspto.gov>; <e-receipt@teas.uspto.gov>  
Sent: Tuesday, April 30, 2002 10:43 AM  
Subject: Received Your Trademark Allegation of Use

<MARK> EARLY ALERT

We have received your Allegation of Use for serial number '78046397'. A summary of your submission is listed below. If you determine that you made an error in the information you entered, DO NOT request via e-mail that we correct your filing. The TEAS staff cannot make any changes. You may file an amendment IMMEDIATELY (if still within the statutory period), via a hard paper copy, not electronically, listing your mark and serial number, and stating your proposed correction, to the following address:

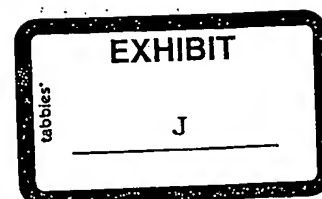
BOX ITU  
Assistant Commissioner for Trademarks  
2900 Crystal Drive  
Arlington, VA 22202

To avoid lateness due to mail delay, it is recommended that you include the following CERTIFICATE OF MAILING language as part of your submission:

I certify that the foregoing is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Assistant Commissioner for Trademarks, 2900 Crystal Drive, Arlington, VA 22202-3513, on

Date of Deposit \_\_\_\_\_  
Signature \_\_\_\_\_  
Name \_\_\_\_\_

-----  
<DOCUMENT INFORMATION>  
<TRADEMARK/SERVICEMARK ALLEGATION OF USE>  
<VERSION 1.24>  
<TRADEMARK/SERVICEMARK INFORMATION>  
<MARK>EARLY ALERT  
<SERIAL NUMBER>78046397  
<APPLICANT INFORMATION>  
<NAME>FMG Innovations Inc.  
<STREET>4250 E. Camelback Rd Suite K-120  
<CITY>Phoenix  
<STATE>AZ  
<COUNTRY>USA





<ZIP/POSTAL CODE>85018  
<NOTICE OF ALLOWANCE INFORMATION>  
<NOTICE OF ALLOWANCE>Yes  
<GOODS AND SERVICES INFORMATION>  
<ALL GOODS AND/OR SERVICES IN APPLICATION/NOTICE OF ALLOWANCE>Yes  
<FEE INFORMATION>  
<TOTAL FEES PAID>100  
<NUMBER OF CLASSES>1  
<USE INFORMATION>  
<INTERNATIONAL CLASS NUMBER>010  
<SPECIMEN>Yes  
<SPECIMEN DESCRIPTION>Retail Product box for EARLY ALERT Alzheimer's Home Screening  
Test  
<FIRST USE ANYWHERE DATE>02/03/2001  
<FIRST USE IN COMMERCE DATE>03/26/2001  
<SIGNATURE AND OTHER INFORMATION>  
<SIGNATURE>/william gartner/  
<DATE>04/30/2002  
<NAME>William J Gartner  
<TITLE>CEO  
<TELEPHONE NUMBER>602-468-0777  
<E-MAIL ADDRESS>wjg@FMGinnovations.com  
<RAM INFORMATION>  
<RAM SALE NUMBER>440  
<SERIAL NUMBER INFORMATION>  
<SERIAL NUMBER>78046397

TEAS support team

Tuesday, 04-30-2002 13:43:24 EDT

STAMP: USPTO/SOU-63228147113-2002043013438670-78046397-  
124be6ce8822d42f0edf0ef6e1ad8cf8525-RAM-440

UNITED STATES DEPARTMENT OF COMMERCE  
ASSISTANT COMMISSIONER FOR TRADEMARKS  
2900 CRYSTAL DRIVE  
ARLINGTON, VIRGINIA 22202-3513  
Jun 13, 2002

NOTICE OF ACCEPTANCE OF STATEMENT OF USE

FMG Innovations, Inc.  
6342 E. Alta Hacienda Dr.  
Scottsdale AZ 85251

TM12

ATTORNEY  
REFERENCE NUMBER:

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SERIAL NUMBER: 78/046397  
MARK: EARLY ALERT  
OWNER: FMG Innovations, Inc.

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The statement of use filed in regard to the above-identified application has been accepted. This acceptance signifies that the statement of use is accepted in all respects and that the mark is entitled to be registered. Accordingly, the registration will issue in due course barring any extraordinary circumstances.

U.S. Patent and Trademark Office (PTO)  
**NOTICE OF ALLOWANCE**

(NOTE: If any data on this notice is incorrect, please submit a written request for correction of the NOA to: Assistant Commissioner for Trademarks, Box 1TU, 2900 Crystal Drive, Arlington, VA 22202-3513. Please include the serial number of your application on ALL correspondence with the PTO. 15 U.S.C. 1063(b)(2))

ISSUE DATE OF NOA: Oct 30, 2001

FMG Innovations, Inc.  
6342 E. Alta Hacienda Dr.  
Scottsdale AZ 85251

**\*\* IMPORTANT INFORMATION: 6 MONTH DEADLINE \*\***

To avoid ABANDONMENT of this application, either a "Statement of Use" (a.k.a. "Allegation of Use") or a "Request for Extension of Time to File a Statement of Use" (a.k.a. "Extension Request") and the appropriate fee(s) must be received in the PTO within six months of the issue date of this Notice of Allowance (NOA) for those goods and/or services based on intent to use. Failure to do so will result in the ABANDONMENT of this application.

Please note that both the "Statement of Use" and "Extension Request" have many legal requirements, including fees. These requirements are explained in the PTO booklet "Basic Facts About Trademarks", which can be obtained upon request at (703)308-9000. In addition, there are printed forms contained in this booklet (for "Statements of Use" and "Extension Requests") for your use.

The following information should be reviewed for accuracy:

SERIAL NUMBER: 78/046397  
MARK: EARLY ALERT  
OWNER: FMG Innovations, Inc.  
6342 E. Alta Hacienda Dr.  
Scottsdale, ARIZONA 85251

This application has the following bases, but not necessarily for all listed goods/services:  
Section 1(a): NO      Section 1(b): YES      Section 44(e): NO

**GOODS/SERVICES BY INTERNATIONAL CLASS**

010-Self administered screening test for Alzheimer's disease and other diseases where measuring the ability to smell can be used as the test method

ALL OF THE GOODS/SERVICES IN EACH CLASS ARE LISTED

ESTUDIO MAY

INVOICE

Client: FMG Innovations Inc.  
6342 E Alta Hacienda Drive  
Scottsdale AZ 85251  
Dr. Steven Feyrer-Melk

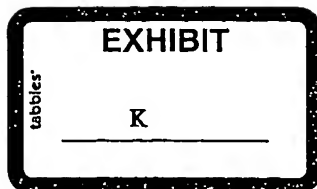
Invoice Number: FMG010038  
Invoice Date: 05/22/01  
Terms: Net due 30 days

Job Description: Early Alert Product Carton  
Final phase billing

Total Fees: 4,875.00  
Total Expenses: 360.00

---

Total Invoice: \$ 5,235.00  
Less prior billings ( 1,745.00)  
Balance due \$ 3,490.00



ESTUDIO RAY

INVOICE

Client: FMG Innovations Inc.  
6342 E Alta Hacienda Drive  
Scottsdale AZ 85251  
Dr. Steven Feyrer-Melk

Invoice Number: FMG01004B

Invoice Date: 05/15/01

Terms: Net due 30 days

Job Description: Early Alert Product Box  
Final Billing

Total Fees: 3,750.00

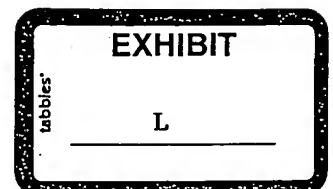
Total Expenses: 300.00

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Total Invoice: \$4,050.00

Less prior billings 1,350.00

Balance due \$ 2,700.00



## Main Identity

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From: "William Gartner" <wilgartner@home.com>  
To: "Chuck Riley" <CRILEY@rileysandilos.com>  
Cc: "Brad Davis" <brad-davis1@home.com>; "Dr. Richard Doty" <doty@mail.med.upenn.edu>  
Sent: Tuesday, November 27, 2001 8:56 AM  
Subject: License Agmt

Dear Chuck:

I left you a message last night that we can agree to a flat rate royalty of \$1.10 per unit only when we have the cost figures on the odor strips. As you know, these are the biggest unknown to us and we need real numbers to plug into our product costs, and thus into our projections, to determine if we can afford the \$1.10 per unit.

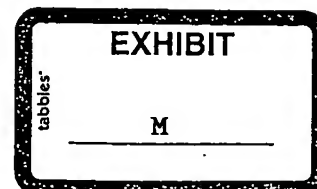
The cost of the odor strips will also determine the amount of cash required to buy Dr. Doty's inventory at Olfactus. The simplest thing will be to provide a copy of the invoice from the supplier, since we will likely use the same vendor.

Pls let me know ASAP so I can let Quarles & Brady proceed with the draft of the License Agmt.

Thanks,

Will

William Gartner, CEO  
FMG Innovations Inc.  
PO Box 1886  
Scottsdale AZ 85252  
866.467.1234 Toll free  
480.949.8390 Direct dial  
480.946.6567 Fax  
[www.FMGinnovations.com](http://www.FMGinnovations.com)  
[wlg@FMGinnovations.com](mailto:wlg@FMGinnovations.com)



11/27/01

## Early Alert™

# Alzheimer's Screening Test

### Background of the Invention

Alzheimer's disease (AD) is a degenerative brain disorder that primarily affects older persons. While the time it takes for Alzheimer's disease to develop will vary from person to person, more advanced symptoms include confusion, language disturbances, personality and behavior changes and impaired judgment. The average life expectancy after diagnosis is 8 years. New drug therapies however, are showing that the earlier that diagnosis occurs, the higher the effectiveness of these drugs in slowing the rate of progress of the disease. The importance of early diagnosis includes:

- A chance to benefit from treatments and medications
- More time to plan for the future
- A possible increase in the quality of life
- Identify the cause of the problem
- A decrease in anxiety

There is no current method for the diagnosis of Alzheimer's disease. A combination of physical, neurological and mental tests is used. The Wechsler Memory test, smell testing and the Mini Mental State Examination are often used to verify the symptoms most often associated with AD. The only true diagnosis for AD occurs at the time of autopsy when the presence of plaques and tangles in the brain is proven.

It has heretofore been known to those skilled in the art that the early onset of Alzheimer's disease (AD) is usually accompanied by a reduction in the olfactory sense. The Harvard Mental Health Letter of June 2001 states, "Recent studies confirm that a deficit in the sense of smell is characteristic of Alzheimer's disease and suggest that people lose awareness of this loss at a very early stage." The loss of the sense of smell has been found to be more reliable in screening for AD than standard cognitive capacity tests. It is also reported that the loss of smell occurs even before Alzheimer's disease can be diagnosed. Specific deficits in odor detection threshold, identification and memory have been recognized in AD which is a neurodegenerative disorder.

There are various "clinical" smell tests available that generally require that the test be administered by a clinician, such as a doctor, nurse or nurse-practitioner. These tests usually are either returned to the manufacturer for scoring purposes or take some significant time by the administrator to score. They are usually accompanied by an administration manual. One example is the 40-item Smell Identification Test of olfactory function. This test, while self-administered, must be scored by an administrator. The test provides an absolute index of smell loss as well as index for detecting malingering and percentile rank of the examinee based upon norms from nearly 4,000 men and women spanning the entire age range. This Smell test is also known as the University of Pennsylvania Smell Identification Test (UPSIT). The test consists of 40 odorants in 4 separate booklets.

**EXHIBIT**

tabbles

N

From the UPSIT came the 12-item version that has been proven to have complete correlation to the 40-item test. Called the Cross Cultural Smell Identification Test (CC-SIT), the test is designed to be completely self-administered, but is to be scored with an administration manual or returned to the manufacturer for scoring. The odors in this test are well known to most everyone in the USA and most non-USA cultures, making it useful in Europe, South America and Asia. Neither the UPSIT nor the CC-SIT have been packaged and sold specifically for the screening of possible Alzheimer's disease.

Numerous published scientific and medial studies have employed the UPSIT and the CC-SIT and a number have found smell loss to be among the first, if not the first, signs of Alzheimer's disease. In some cases these studies have demonstrated that such loss more or less predicts who, among at-risk individuals, will likely eventually develop AD.

The Early Alert™ Alzheimer's Home Screening Test is a smell test that allows an individual to determine if a loss of olfactory function is present. Although a lot all older persons with smell loss have AD, such loss, alone or in combination with memory problems and/or certain genetic markers, is among the best predictors or indicators of AD. Early Alert™ has been designed to assist in early detection of possible AD by determining if a person has a degraded sense of smell. Failing the test does not necessarily mean one has AD. If one fails the test, it is recommended that one sees his or her physician.

#### **Detailed Description of the Invention**

The test is a booklet approximately 3¼ by 6½ inches. The booklet is oriented for use in the "landscape" layout. The booklet has a front cover, an inside front cover, an inside back cover, an outside back cover and 12 individual inside pages.

The cover has the product name, Early Alert™ Alzheimer's Home Screening Test and two additional statements. The first is labeled IMPORTANT "Information booklet provided. Read the entire booklet prior to beginning the screening test. Follow the instructions carefully." The second is a marketing tagline "Have you ever wondered."

The inside front cover lists 8 very important facts and instructions in bullet form.

- Smell loss is among the first signs of Alzheimer's disease; this screening test measures your ability to smell.
- Do not attempt this screening test if you currently have nasal congestion or long lasting smell loss due to other known causes.
- Do not scratch the odor strip until you are ready to sniff the odor.
- Poor performance on this screening test does not necessarily mean you have Alzheimer's disease.
- This screening test works only if the directions are followed precisely as noted.
- This screening test can only be used one time and prior to the expiration date. Discard after use.



- Decreased olfactory function (sense of smell) is not the only indicator of potential Alzheimer's disease.
- Decreased olfactory function (sense of smell) can be found in older individuals without Alzheimer's disease.

Eleven of the inside pages have no printing on the back while the last page, the 12<sup>th</sup>, does have printing on the back. The pages all have the same format consisting of word and picture instructions on how to take the test. These instructions are printed on the left half of each page and repeated on all 12 pages.

The instructions are as follows:

1. Use pencil provided, scratch odor strip in ZIG-ZAG. (a small graphic is included)
2. Place odor strip directly under both nostrils and sniff. (a small graphic is included)
3. Circle best answer. You must circle one answer. (a small graphic is included)
4. Turn the page.

Each page is numbered, e.g. Odor #1, Odor #2, etc. On the right half of each page the question "This odor smells most like:" is repeated and is followed by a listing of four possible "names" for the odorant on that page. For example Odor #7 lists watermelon, peanut, rose and paint thinner as the possible odors. The correct answer is paint thinner. A note under the question "This odor smells most like:" requests that the user "Circle one".

The back of the page of Odor #12 has two printed sections. The first is "Scoring the Test" and the second is Reading the Results. The inside back cover faces the back of page Odor #12 and contains the Answer Key". This is a listing of all of the correct odors on each of the Odor pages. For example, Odor #1 is cinnamon; Odor #2 is turpentine, etc.

The test itself is 12 microencapsulated smell strips that are "scratched" to release an odor. A person sniffs the strip and chooses one of four possible answers shown on that page.

"Scoring the Test" instructs the user to look at the Answer Key. It then asks the user to compare each of his or her circled answers on each odor page to the Answer Key, instructing the user to "put a line through the answer if the selection and the answer do not match. Then after comparing all of the Odor pages to the Answer Key, the user is asked to total the number of odors that are incorrect or have a line through them and write that number in the box provided on the Answer Key page.

"Reading the Results" states "If you have 4 or more incorrect items you should consult your physician." It also suggests that if the user does not have 4 or more incorrect answers but is experiencing symptoms of AD, he or she should contact a physician. Additional caveats are printed here, such as "Early Alert™ is not a diagnostic test nor a conclusive test for Alzheimer's disease."

The outside back cover gives 6 storage and handling instructions, the Company name, phone number and the statement Patent Pending.

Claim 3 might be:

The test kit in Claim 2 wherein the scoring of the test is contained on a page at the end of the test book where the correct answers are given and a box is provided to enter the number of smells identified incorrectly.

The purpose in making the very, very broad Claim 1, is first to see if you can get the broadest possible claim allowed – "a possibility" says partner Robert Atkins. If the patent is rejected, and this is a good possibility, we immediately drop Claim 1 and proceed. I have used this tactic in previous patent applications and it works well.

Additional issues include:

1. We will need to compile all of the statistical information that states that 4 or more incorrect answers equate to failing the test. This would end up as a claim. Of course we need Dr. Doty's assistance with this.
2. We can immediately proceed with filing the patent in Canada and probably Japan. There are possible issues with the foreign patents in Europe due to our sales on the Internet. However, we will be filing a second patent to take care of that (see below).
3. We need to send a list of countries in which we want to file for foreign patents
4. Need dates for conference call with Dr. Doty after he sends the statistics
5. Additional retainer

It is our plan to immediately file a second patent with Davis, Doty, Feyrer-Melk and Gartner as the inventors, which will be an improvement or continuation in part of the first. It will likely add claims for a process wherein all of the pages of the booklets are printed at one time with a second press applying the "scented ink", thus eliminating the hand application of self-adhesive scented labels.

We might also add another claim to make the Answer Key or Scoring Page a fold out so the user does not have to flip back and forth to score the test.

The purpose in filing a second application is to clear the way for filing foreign patents in all desired countries. This will greatly strengthen our patent position.

We have the booklet marked as copyrighted. They attorneys suggest that we file a federal copyright on it for stronger protection.

**IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE**

In re Application of: Gartner, William	)	
	)	
Title: Self-Scoring Method and	)	
Apparatus for Early Self-	)	Examiner: Suhol, Dmitry
Screening of Neurological	)	
Disease	)	Art Unit: 3712
	)	
Serial No.: 10/015,442	)	
	)	
Date: 12/13/2001	)	

**AFFIDAVIT OF WILLIAM GARTNER**  
**UNDER 37 C.F.R. § 1.131**

I, William Gartner, of full age, do hereby attest as follows:

1. I am a co-inventor of the invention claimed in the application referenced above (the "Application"). As such, I am fully familiar with the facts set forth below.
2. Steven Feyrer-Melk, the other co-inventor of the invention claimed in the Application, and I conceived the invention claimed in the Application before April 2, 2001, the filing date of U.S. Publication No. 2002/0139170A1 of Doty ("Doty").
3. A description of the apparatus and method of the invention is documented under the heading "Instructions for Early Alert™ Alzheimer's Home Screening Test," which is attached hereto as Exhibit A. As the Instructions expressly provide, the apparatus of the invention comprises a booklet, a plurality of pages, a plurality of smell labels, instructions for scoring, a structure whereby an answer may be circled, an answer key, and instructions for interpreting the score achieved. In addition, the Instructions describe the steps of the method of the invention, including providing an odor-containing source capable of releasing an odor (2), providing a plurality of choices of possible identity of the odor-containing source (3 and 4), providing an answer key (6), and providing an instruction for self-scoring (6, 7 and footnote \*). The

document attached as Exhibit A is a copy of the original which was created on February 4, 2001, nearly two (2) months prior to the filing date of Doty.

4. An example of the plurality of labels from which a user of the invention may select an answer is provided in the document attached hereto as Exhibit B. The document attached hereto as Exhibit B is a copy of the original which was created on January 10, 2001, nearly three (3) months prior to the filing date of Doty.

5. An example of an answer key according to the invention claimed in the Application is provided in the document attached hereto as Exhibit C. The document attached hereto as Exhibit C is a copy of the original which was created on February 4, 2001, nearly two (2) months prior to the filing date of Doty.

6. Additional instructions regarding self-scoring according to the invention claimed in the Application is provided in the document attached hereto as Exhibit D. The document attached hereto as Exhibit D is a copy of the original which was created on January 21, 2001, more than two (2) months before the filing date of Doty.

7. Additional evidence of the conception of the invention claimed in the Application is provided by the product packaging, which is attached hereto as Exhibit E. The document attached hereto as Exhibit E is a copy of the original which was created on December 29, 2000, more than three (3) months prior to the filing date of Doty.

8. Additional evidence of the conception of the invention claimed in the Application is provided by the "Information Olfactory Function and Alzheimer's Disease," which is attached hereto as Exhibit F. The document attached hereto as Exhibit F is a copy of the original which was created on February 4, 2001, nearly two (2) months prior to the filing date of Doty.

9. Additional evidence of the conception of the invention claimed in the Application is provided by the summary outline entitled "Alzheimer's Meeting (SAFM Home Office) Will Gartner and Steven Feyrer-Melk," which is attached hereto as Exhibit G. The document attached hereto as Exhibit G is a copy of the original which was created on November 20, 2000, more than four (4) months prior to the filing date of Doty.

10. Each of the documents attached hereto as Exhibits A through G were created in the United States of America. Further, the invention was completed in the United States of America prior to April 2, 2001, the filing date of Doty. In addition, Doty has not resulted in an issued patent. Consequently, the issue date of Doty is not more than one (1) year prior to the filing date of the Application, December 13, 2001. In fact, the filing date of the Application precedes the publication date of Doty, October 3, 2002, by nearly one (1) year.

11. The co-inventors of the invention claimed in the Application exercised due diligence from prior to the filing date of Doty until the filing date of the Application. More particularly, the co-inventors of the invention claimed in the Application exercised due diligence from April 1, 2001 until December 13, 2001. By way of illustration, between April 1, 2001 and December 13, 2001, the co-inventors engaged in the following activities:

- worked through quality control issues concerning the manufacture of the test smell strips (*See Exhibit H*);
- analyzed and modified the scoring sensitivity and specificity of the smell test (*See Exhibit I*);
- pursued and obtained a trademark for the mark Early Alert® (*See Exhibit J*);
- developed an Early Alert® product carton (*See Exhibit K*);
- developed an Early Alert® product box (*See Exhibit L*);

- negotiated royalty rates and licensing agreements for the product (*See Exhibit M*); and
- assisted patent counsel in the preparation of the application that was ultimately filed on December 13, 2001 (*See Exhibit N*).

12. I submit this Affidavit under 37 C.F.R. 1.131 in support of the removal of Doty and the patent that resulted therefrom as valid prior art references cited against the Application.

13. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

---

William Gartner, co-inventor

Sworn to and subscribed before me  
this \_\_\_\_ day of May, 2003.

---

Notary Public

My Commission Expires: \_\_\_\_\_

- negotiated royalty rates and licensing agreements for the product (*See Exhibit M*); and
- assisted patent counsel in the preparation of the application that was ultimately filed on December 13, 2001 (*See Exhibit N*).

12. I submit this Affidavit under 37 C.F.R. 1.131 in support of the removal of Doty and the patent that resulted therefrom as valid prior art references cited against the Application.

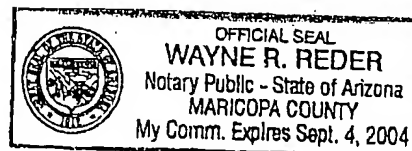
13. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

William Gartner  
William Gartner, co-inventor

Sworn to and subscribed before me  
this 19th day of May, 2003.

Wayne R. Reder  
Notary Public

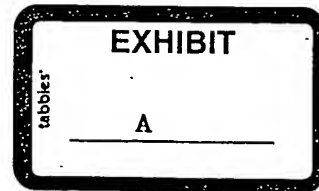
My Commission Expires: Sept. 04, 2004



## INSTRUCTIONS FOR EARLY ALERT™ ALZHEIMER'S HOME SCREENING TEST\*

1. DO NOT ATTEMPT THE TEST IF YOU CURRENTLY HAVE NASAL CONGESTION OR LONG-STANDING SMELL LOSS DUE TO HEAD TRAUMA OR OTHER KNOWN CAUSES
2. GO TO THE FIRST PAGE OF THE TEST (SMELL #1) AND SCRATCH THE COLORED SMELL LABEL WITH A PENCIL FROM LEFT TO RIGHT SEVERAL TIMES IN A ZIG-ZAG FASHION TO RELEASE THE ODOR. THEN PLACE THE LABEL OVER BOTH NOSTRILS AND SNIFF IT.
3. CIRCLE THE BEST ANSWER; IF NOT SURE OR NO SMELL IS PRESENT, TRY TO GUESS ANYWAY
4. CONTINUE UNTIL ALL 12 SMELL LABELS HAVE BEEN SNIFFED AND AN ANSWER HAS BEEN CIRCLED FOR EACH
6. AFTER COMPLETION OF THE TEST, TURN TO THE ANSWER KEY ON THE LAST PAGE OF THE BOOK AND DETERMINE YOUR TEST SCORE (I.E., HOW MANY OF THE 12 ITEMS YOU MISSED)
7. IF YOU MISSED MORE THAN TWO ITEMS, YOU SHOULD CONTACT YOUR PHYSICIAN FOR FURTHER EVALUATION

\*See last page of the test booklet for further information concerning the interpretation of the results.



1012

Created on 2/04/01



1. This odor smells most like

- a. gasoline
- b. pizza
- c. peanuts
- d. lilac

4. This odor smells most like

- a. dill pickle
- b. bubble gum
- c. wintergreen
- d. watermelon

7. This odor smells most like

- a. tomato
- b. licorice
- c. strawberry
- d. menthol

10. This odor smells most like

- a. whiskey
- b. honey
- c. lime
- d. cherry

2. This odor smells most like

- a. gasoline
- b. pizza
- c. peanuts
- d. lilac

5. This odor smells most like

- a. dill pickle
- b. bubble gum
- c. wintergreen
- d. watermelon

8. This odor smells most like

- a. tomato
- b. licorice
- c. strawberry
- d. menthol

11. This odor smells most like

- a. whiskey
- b. honey
- c. lime
- d. cherry

3. This odor smells most like

- a. gasoline
- b. pizza
- c. peanuts
- d. lilac

6. This odor smells most like

- a. dill pickle
- b. bubble gum
- c. wintergreen
- d. watermelon

9. This odor smells most like

- a. tomato
- b. licorice
- c. strawberry
- d. menthol

12. This odor smells most like

- a. whiskey
- b. honey
- c. lime
- d. cherry



EARLY ALERT™ SCORING KEY (CORRECT ANSWERS)

ODOR #1 - B. CINNAMON

ODOR #2 - A. TURPENTINE

ODOR #3 - D. LEMON

ODOR #4 - C. SMOKE

ODOR #5 - B. CHOCOLATE

ODOR #6 - B. ROSE

ODOR #7 -- D. PAINT THINNER

ODOR #8 - A. BANANA

ODOR #9 - C. PINEAPPLE

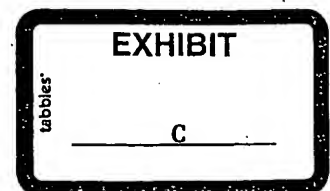
ODOR #10 - D. GASOLINE

ODOR #11 - A. SOAP

ODOR #12 - C. ONION

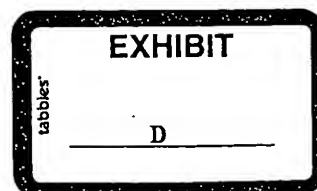
1012

Created on 2/04/01

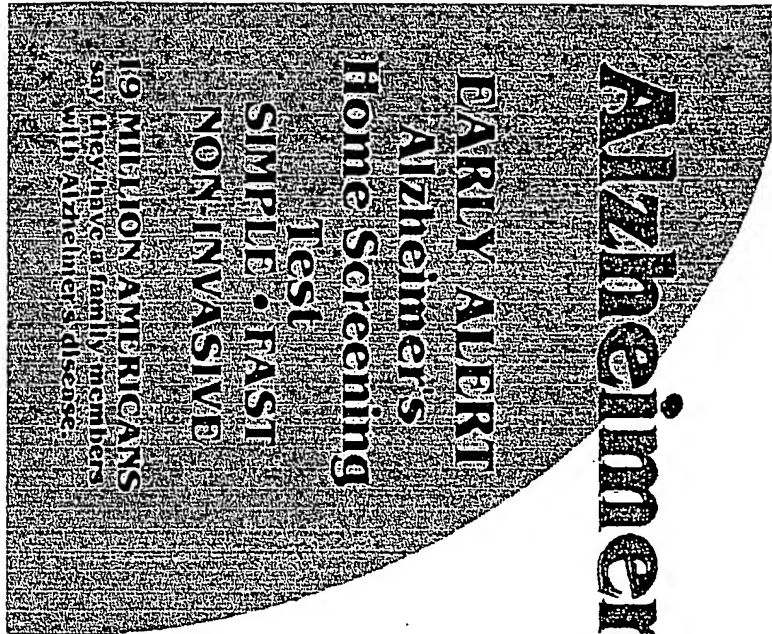


Please Note: (Disclaimer)

1. Early Alert Alzheimer's Home Screening has been designed to assist in early detection of possible Alzheimer's disease. False positives are possible with this test.
2. Failing the Early Alert Alzheimer's Home Screening does not mean you have Alzheimer's disease. Early Alert Alzheimer's Home Screening is NOT a diagnostic test nor a conclusive test for Alzheimer's disease. You must follow up by seeing a physician.
3. If you have any reason to believe you may have Alzheimer's Disease, see a doctor.



created on 01/21/01



16 MILLION AMERICANS  
say they have a family member  
with Alzheimer's disease

**EARLY ALERT**  
**Alzheimer's**  
**Home Screening**  
**Test**  
**SIMPLE • FAST**  
**NON-INVASIVE**

# Alzheimer's Disease Screening

Did you ever wonder?

- Memory loss affecting job skills?
- Difficulty performing familiar tasks?
- Misplacing things?

[www.AlzheimerTestKit.com](http://www.AlzheimerTestKit.com)  
1-800-123-4567



**EARLY ALERT**  
**Alzheimer's Home Screening**  
[www.AlzheimerTestKit.com](http://www.AlzheimerTestKit.com)  
**SIMPLE • FAST • NON-INVASIVE**

## DISCLAIMER:

1. Early Alert Alzheimer's Home Screening is not a conclusive test for Alzheimer's Disease.
2. False positives are possible with this test.
3. Early Alert Alzheimer's Home Screening has been designed to assist in early detection of Possible Alzheimer's Disease.



4. Only a qualified medical professional is NOT an Alzheimer's Disease diagnostic test and you MUST follow up by seeing a physician.
5. Failing the Early Alert Alzheimer's Home Screening does not mean you have Alzheimer's Disease.
6. If you have any reason to believe you may have Alzheimer's Disease, see a doctor.

EXHIBIT

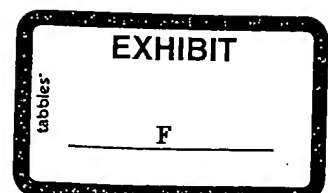
E

created 12/29/00

## INFORMATION ABOUT OLFACTORY FUNCTION AND ALZHEIMER'S DISEASE

Smell loss is among the first signs of Alzheimer's disease (AD). Although not all older persons with smell loss have AD, such loss -- alone or in combination with memory problems and/or certain genetic markers -- is among the best predictors or indicators of AD. Early Alert™ has been designed to assist in early detection of possible Alzheimer's disease. However, false positives and false negatives are possible with this test. Failing this test does not mean you have Alzheimer's disease. Early Alert™ is NOT a diagnostic test nor a conclusive test for Alzheimer's disease. Nonetheless, poor performance on this test should be followed up by evaluation by a physician. Medical and scientific studies on smell function and AD include:

Bacon et al. (1998) Very early changes in olfactory functioning due to Alzheimer's disease and the role of apolipoprotein E in olfaction. *Ann NY Acad Sci* 855, 723-751; Devanand DP et al (2000) Olfactory deficits in patients with mild cognitive impairment predict Alzheimer's disease at follow-up. *Amer J Psychiat* 157, 1399-1405; Doty RL et al (1987) Presence of both odor identification and detection deficits in Alzheimer's disease. *Brain Res Bull* 18, 597-600; Doty et al. (1991) Olfactory dysfunction in three neurodegenerative diseases. *Geriatrics* 46 (Suppl 1), 47-51; Graves AB et al. (1999) Impaired olfaction as a marker for cognitive decline: interaction with apolipoprotein E epsilon4 status. *Neurology* 53, 1480-1487; McCaffrey RJ et al. (2000) Olfactory dysfunction discriminates probable Alzheimer's dementia from major depression: A cross validation and extension. *J Neuropsychiat Clin Neurosci* 12, 29-33; Murphy C et al (1998) Apolipoprotein E status is associated with odor identification deficits in nondemented older persons. *Ann NY Acad Sci* 855, 744-750; Serby M et al (1991) The nature and course of olfactory deficits in Alzheimer's disease. *Amer J Psychiat* 148, 357-360; Serby et al (1996) Olfactory identification deficits in relatives of Alzheimer's disease patients. *Biol Psychiat* 39, 375-377; Solomon GS et al (1998) Olfactory dysfunction discriminates probable Alzheimer's dementia from major depression. *J Neuropsychiat Clin Neurosci* 10, 64-67.



11/20/00

**Alzheimer's Meeting (SAFM Home Office)  
Will Gartner & Steven Feyrer-Melk**

Discussed AD test

Discussed conversation with Dr. Doty from Sonsonics

Discussed next steps for product

Letter to Doty

We provide material they deposit smell

Quote

100

Can they be sealed in plastic shrink wrap

Susan will write disclaimer

Needs sample tests

Needs research

Discussed Test

Miss 2 or more contact a physician

Discussed Format of test

2 fold

Front Cover with name

Inside cover directions (why test smell)

Bottom inside smells with blanks

Back waiver/disclaimer and answers behind tape

Buy sample tests

Discussed list of "things to do"

Disclaimers

See Medical Attorney

Develop prototype

Website Development

Packaging

Trip to Sonsonics

Advertisement (AARP, Suncity cities, papers)

Think of Names

Early Alert

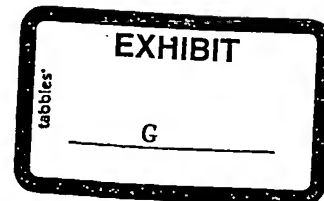
Early Alert Alzheimer's Test

Alzheimer's Home Screening Test

Discussed pricing

(Use Alzheimer's fact sheet, statement of science behind the test)

Question: What if someone takes the test and does harm to themselves? Could be psychologically powerful.



revised 11/20/2000

Subj: Re: Shipments received  
 Date: 5/21/01 2:27:17 PM US Mountain Standard Time  
 From: doty@mail.med.upenn.edu (Richard L. Doty Ph.D.)  
 To: WilGartner@aol.com

Dear Will:

Thanks for the feedback regarding the tests; I will implement a closer quality control on the production and will review what gets sent out. I have talked to the company who is manufacturing the tests and will also review the remaining tests to be sent out.

Sorry for these problems. I'm responding to your other e-mail now.

Dick

At 02:04 AM 5/21/2001 EDT, you wrote:

>Dick:

>

>WE received a shipment on Saturday of 200 Test Kits that have the Sensonics

>Smell STRips (all brown). Of the 200 4 were rejected because three were

>missing one smell strips and one had an improperly placed smell strip.

>

>We received a shipment of 225 Test Kits on Sunday that have the new Smell

> Of these, 76 were

>rejected for one or more of the following reasons:

>

> Missing a smell strip (~3 kits)

>

> (~5 kits)

>

> No white out tape (~190 kits)

>

> smell strip very crooked (~40)

>

> Outside back cover is blurry (~4 kits)

>

> Incorrect smell strip pulled off, tearing or peeling the paper, and a new

>smell strip put in its place. (~6)

>

>We need to discuss the implementation of stronger quality control measures.

>While we went through all 400 test kits, we don't relish the idea of going

>through 10,000 let alone 68,000 when we get the Walgreens order.

>

>May we please have your thoughts on these issues in a phone conversation

>Monday afternoon between 1 and 3 PM PHX time.

>

>Thanks for getting the kits to us for the Walgreens presentation. We will use

>the colored smell strips units for that.

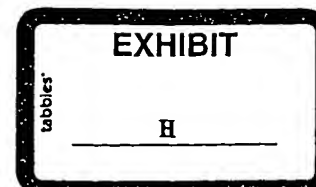
>

>Thanks,

>

>Will

>



Subj: **BIG PROBLEM**  
 Date: 5/10/01 10:11:29 PM US Mountain Standard Time  
 From: safm.phd@home.com (Steven A. Feyrer-Melk, Ph.D.)  
 To: WilGartner@aol.com (WilGartner@aol.com)

Will,

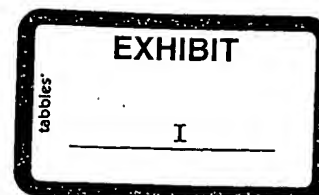
We need to TALK! This is a problem.

Return-Path: <doty@mail.med.upenn.edu>  
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 by mail1.rdc1.az.home.com  
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 for <safm.phd@mail.phnx1.az.home.com>;  
 Thu, 10 May 2001 21:31:28 -0700  
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 by mh6-tx.mail.home.com (8.9.3/8.9.0) with ESMTP id VAA10047  
 for <safm.phd@home.com>; Thu, 10 May 2001 21:31:28 -0700 (PDT)  
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 by mx6-tx.mail.home.com (8.11.1/8.11.1) with ESMTP id f4B4VRR22248  
 for <safm.phd@home.com>; Thu, 10 May 2001 21:31:27 -0700 (PDT)  
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 by dolphin.upenn.edu (8.11.1/8.10.1) with SMTP id f4B4VQ108376;  
 Fri, 11 May 2001 00:31:26 -0400 (EDT)  
 Message-Id: <3.0.6.32.20010511003143.00ac7ac0@mail.med.upenn.edu>  
 X-Sender: doty@mail.med.upenn.edu  
 X-Mailer: QUALCOMM Windows Eudora Light Version 3.0.6 (32)  
 Date: Fri, 11 May 2001 00:31:43 -0400  
 To: sfm@FMGinnovations.com, safm.phd@home.com  
 From: "Richard L. Doty Ph.D." <doty@mail.med.upenn.edu>  
 Subject: cut off for concern on test  
 Mime-Version: 1.0  
 Content-Type: text/plain; charset="us-ascii"  
 X-Mozilla-Status2: 00000000

Steve -- I have gone back and looked carefully at the cut-off score we proposed for the test. A cut-off of 3 (i.e., a score of 9) I believe is somewhat too liberal. While being high on sensitivity, it would be quite low on specificity and would lead to far too many false positives.

Looking at the norms for the 12-item test and going back to my 1987 AD paper, I think we need to have as the criterion for seeing a physician a somewhat different number. Here is my reasoning.

In the 1987 paper and elsewhere, the average UPSIT score for AD patients is around  $20/40 = 50\%$  of the total score. Therefore, the average B-SIT score for an AD patient would be 50% of 12 or about 6 wrong. In determining an upper range, if we look at the range of scores in the AD patients, and look at the upper few scores and accept a small degree of overlap, they are around 28/40 or so on the UPSIT (62.5%). Hence, the highest score where we would start being concerned about AD on the B-SIT would be 62.5% of 12 or 7.5; hence,  $12 - 7.5 = 4.5$  wrong. Thus, a cut-off of 5 would probably be a better indicator than a cut-off of 3.





This has considerable ramifications. Looking at the percentiles in the 1996 Laryngoscope paper, the following would apply using 3 wrong (9 right) as the cutoff for the older age groups:

Age:	60-64, 65-69, 70-74, 75-79, 80-84, and >84 yrs
Male %ile:	21 34 45 43 71 77
Female %ile:	10 14 34 48 64 69

If we accept, however, a cut off of 5 wrong (7 right), there corresponding percentile figures would be as follows:

Age:	60-64, 65-69, 70-74, 75-79, 80-84, and >84 yrs
Male %ile:	12 19 23 28 48 56
Female %ile:	04 03 10 25 40 40

If you compare the number of subjects who would seek medical help, the percentage differences between the two groups would be as follows (the numbers represent the percentage more who would be seeking help under the current criteria of 3 wrong):

Age:	60-64, 65-69, 70-74, 75-79, 80-84, and >84 yrs
Male %:	9% 15% 22% 15% 23% 21%
Female %:	6% 11% 24% 23% 24% 29%

These numbers are considerable. For example, if one accepts the notion that the percentages largely reflect a false positive rate, in most of the older age categories we decrease the false positive rate by over 20% by changing the criterion to 5 rather than 3 wrong. While one could argue that it is better to have a false positive than a false negative, the specificity of the test becomes suspect.

My feeling is that we should change the criteria from 3 to 5 at this point, even if we have to put little labels over the first batch of tests to minimize criticism and a statistical criticism of the testing. Alternatively, this could all be explained in the inserts and a simple explanation of what I present above presented.

Your thoughts are appreciated. I am responding to some of the comments of critics that missing three items may not be so difficult. This forced me to re-examine the original assumptions, and I think it would be prudent to change the criterion or provide alternative criteria in the instruction set.

Dick

Richard L. Doty, Ph.D.  
 Professor & Director  
 Smell & Taste Center  
 University of Pennsylvania Medical Center  
 5 Ravdin Building  
 3400 Spruce Street  
 Philadelphia, PA 19104  
 Phone: 215-662-6580  
 FAX: 215-349-5266  
 e-mail: doty@mail.med.upenn.edu

----- Headers -----

Return-Path: <safrn.phd@home.com>

Friday, May 11, 2001 America Online: WilGartner

willgartner@qwest.net

From: "Trademark Electronic Application System TEAS service" <PrinTEAS@uspto.gov>  
 To: <wjg@FMGinnovations.com>  
 Cc: <teas@uspto.gov>; <e-receipt@teas.uspto.gov>  
 Sent: Tuesday, April 30, 2002 10:43 AM  
 Subject: Received Your Trademark Allegation of Use

<MARK> EARLY ALERT

We have received your Allegation of Use for serial number '78046397'. A summary of your submission is listed below. If you determine that you made an error in the information you entered, DO NOT request via e-mail that we correct your filing. The TEAS staff cannot make any changes. You may file an amendment IMMEDIATELY (if still within the statutory period), via a hard paper copy, not electronically, listing your mark and serial number, and stating your proposed correction, to the following address:

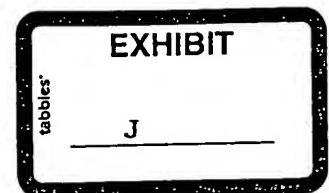
BOX ITU  
 Assistant Commissioner for Trademarks  
 2900 Crystal Drive  
 Arlington, VA 22202

To avoid lateness due to mail delay, it is recommended that you include the following CERTIFICATE OF MAILING language as part of your submission:

I certify that the foregoing is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Assistant Commissioner for Trademarks, 2900 Crystal Drive, Arlington, VA 22202-3513, on \_\_\_\_\_

Date of Deposit \_\_\_\_\_  
 Signature \_\_\_\_\_  
 Name \_\_\_\_\_

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 <SERIAL NUMBER>78046397  
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 <NAME>FMG Innovations Inc.  
 <STREET>4250 E. Camelback Rd Suite K-120  
 <CITY>Phoenix  
 <STATE>AZ  
 <COUNTRY>USA



<ZIP/POSTAL CODE>85018  
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Test  
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<SIGNATURE>/william gartner/  
<DATE>04/30/2002  
<NAME>William J Gartner  
<TITLE>CEO  
<TELEPHONE NUMBER>602-468-0777  
<E-MAIL ADDRESS>wjg@FMGinnovations.com  
<RAM INFORMATION>  
<RAM SALE NUMBER>440  
<SERIAL NUMBER INFORMATION>  
<SERIAL NUMBER>78046397

TEAS support team  
Tuesday, 04-30-2002 13:43:24 EDT

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STAMP: USPTO/SOU-63228147113-2002043013438670-78046397-  
124be6ce8822d42f0edf0ef6e1ad8cf8525-RAM-440

UNITED STATES DEPARTMENT OF COMMERCE  
ASSISTANT COMMISSIONER FOR TRADEMARKS  
2900 CRYSTAL DRIVE  
ARLINGTON, VIRGINIA 22202-3513  
Jun 13, 2002

NOTICE OF ACCEPTANCE OF STATEMENT OF USE

FMG Innovations, Inc.  
6342 E. Alta Hacienda Dr.  
Scottsdale AZ 85251

TM12

ATTORNEY  
REFERENCE NUMBER:

---

SERIAL NUMBER: 78/046397  
MARK: EARLY ALERT  
OWNER: FMG Innovations, Inc.

---

The statement of use filed in regard to the above-identified application has been accepted. This acceptance signifies that the statement of use is accepted in all respects and that the mark is entitled to be registered. Accordingly, the registration will issue in due course barring any extraordinary circumstances.

U.S. Patent and Trademark Office (PTO)  
**NOTICE OF ALLOWANCE**

(NOTE: If any data on this notice is incorrect, please submit a written request for correction of the NOA to: Assistant Commissioner for Trademarks, Box 1TU, 2900 Crystal Drive, Arlington, VA 22202-3513. Please include the serial number of your application on ALL correspondence with the PTO, 15 U.S.C. 1063(b)(2))

ISSUE DATE OF NOA: Oct 30, 2001

FMG Innovations, Inc.  
6342 E. Alta Hacienda Dr.  
Scottsdale AZ 85251

**\*\* IMPORTANT INFORMATION: 6 MONTH DEADLINE \*\***

To avoid ABANDONMENT of this application, either a "Statement of Use" (a.k.a. "Allegation of Use") or a "Request for Extension of Time to File a Statement of Use" (a.k.a. "Extension Request") and the appropriate fee(s) must be received in the PTO within six months of the issue date of this Notice Of Allowance (NOA) for those goods and/or services based on intent to use. Failure to do so will result in the ABANDONMENT of this application.

Please note that both the "Statement of Use" and "Extension Request" have many legal requirements, including fees. These requirements are explained in the PTO booklet "Basic Facts About Trademarks", which can be obtained upon request at (703)308-9000. In addition, there are printed forms contained in this booklet (for "Statements of Use" and "Extension Requests") for your use.

The following information should be reviewed for accuracy:

SERIAL NUMBER: 78/046397  
MARK: EARLY ALERT  
OWNER: FMG Innovations, Inc.  
6342 E. Alta Hacienda Dr.  
Scottsdale, ARIZONA 85251

This application has the following bases, but not necessarily for all listed goods/services:  
Section 1(a): NO      Section 1(b): YES      Section 44(e): NO

**GOODS/SERVICES BY INTERNATIONAL CLASS**

010-Self administered screening test for Alzheimer's disease and other diseases where measuring the ability to smell can be used as the test method

ALL OF THE GOODS/SERVICES IN EACH CLASS ARE LISTED

ESTUDIO RAY

INVOICE

Client: FMG Innovations Inc.  
6342 E Alta Hacienda Drive  
Scottsdale AZ 85251  
Dr. Steven Feyrer-Melk

Invoice Number: FMG01003B

Invoice Date: 05/22/01

Terms: Net due 30 days

Job Description: Early Alert Product Carton  
Final phase billing

Total Fees: 4,875.00

Total Expenses: 360.00

Total Invoice: \$ 5,235.00

Less prior billings ( 1,745.00)

Balance due \$ 3,490.00



 ENTERED

ESTUDIO RAY

INVOICE

Client: FMG Innovations Inc.  
6342 E Alta Hacienda Drive  
Scottsdale AZ 85251  
Dr. Steven Feyrer-Melk

Invoice Number: FMG01004B

Invoice Date: 05/15/01

Terms: Net due 30 days

Job Description: Early Alert Product Box  
Final Billing

Total Fees: 3,750.00

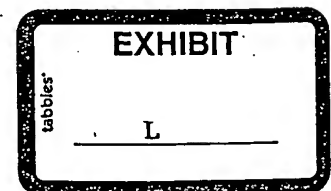
Total Expenses: 300.00

---

Total Invoice: \$4,050.00

Less prior billings 1,350.00

Balance due \$ 2,700.00



## Main Identity

---

**From:** "William Gartner" <wilgartner@home.com>  
**To:** "Chuck Riley" <CRILEY@rileysandilos.com>  
**Cc:** "Brad Davis" <brad-davis1@home.com>; "Dr. Richard Doty" <doty@mail.med.upenn.edu>  
**Sent:** Tuesday, November 27, 2001 8:56 AM  
**Subject:** License Agrmt

Dear Chuck:

I left you a message last night that we can agree to a flat rate royalty of \$1.10 per unit only when we have the cost figures on the odor strips. As you know, these are the biggest unknown to us and we need real numbers to plug into our product costs, and thus into our projections, to determine if we can afford the \$1.10 per unit.

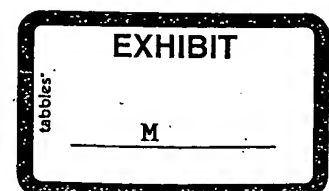
The cost of the odor strips will also determine the amount of cash required to buy Dr. Doty's inventory at Olfactus. The simplest thing will be to provide a copy of the invoice from the supplier, since we will likely use the same vendor.

Pls let me know ASAP so I can let Quarles & Brady proceed with the draft of the License Agmt.

Thanks,

Will

William Gartner, CEO  
FMG Innovations Inc.  
PO Box 1886  
Scottsdale AZ 85252  
866.467.1234 Toll free  
480.949.8390 Direct dial  
480.946.6567 Fax  
[www.FMGinnovations.com](http://www.FMGinnovations.com)  
[wjg@FMGinnovations.com](mailto:wjg@FMGinnovations.com)





## Early Alert™

# Alzheimer's Screening Test

### Background of the Invention

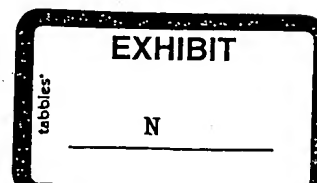
Alzheimer's disease (AD) is a degenerative brain disorder that primarily affects older persons. While the time it takes for Alzheimer's disease to develop will vary from person to person, more advanced symptoms include confusion, language disturbances, personality and behavior changes and impaired judgment. The average life expectancy after diagnosis is 8 years. New drug therapies however, are showing that the earlier that diagnosis occurs, the higher the effectiveness of these drugs in slowing the rate of progress of the disease. The importance of early diagnosis includes:

- A chance to benefit from treatments and medications
- More time to plan for the future
- A possible increase in the quality of life
- Identify the cause of the problem
- A decrease in anxiety

There is no current method for the diagnosis of Alzheimer's disease. A combination of physical, neurological and mental tests is used. The Wechsler Memory test, smell testing and the Mini Mental State Examination are often used to verify the symptoms most often associated with AD. The only true diagnosis for AD occurs at the time of autopsy when the presence of plaques and tangles in the brain is proven.

It has heretofore been known to those skilled in the art that the early onset of Alzheimer's disease (AD) is usually accompanied by a reduction in the olfactory sense. The Harvard Mental Health Letter of June 2001 states, "Recent studies confirm that a deficit in the sense of smell is characteristic of Alzheimer's disease and suggest that people lose awareness of this loss at a very early stage." The loss of the sense of smell has been found to be more reliable in screening for AD than standard cognitive capacity tests. It is also reported that the loss of smell occurs even before Alzheimer's disease can be diagnosed. Specific deficits in odor detection threshold, identification and memory have been recognized in AD which is a neurodegenerative disorder.

There are various "clinical" smell tests available that generally require that the test be administered by a clinician, such as a doctor, nurse or nurse-practitioner. These tests usually are either returned to the manufacturer for scoring purposes or take some significant time by the administrator to score. They are usually accompanied by an administration manual. One example is the 40-item Smell Identification Test of olfactory function. This test, while self-administered, must be scored by an administrator. The test provides an absolute index of smell loss as well as index for detecting malingering and percentile rank of the examinee based upon norms from nearly 4,000 men and women spanning the entire age range. This Smell test is also known as the University of Pennsylvania Smell Identification Test (UPSIT). The test consists of 40 odorants in 4 separate booklets.



From the UPSIT came the 12-item version that has been proven to have complete correlation to the 40-item test. Called the Cross Cultural Smell Identification Test (CC-SIT), the test is designed to be completely self-administered, but is to be scored with an administration manual or returned to the manufacturer for scoring. The odors in this test are well known to most everyone in the USA and most non-USA cultures, making it useful in Europe, South America and Asia. Neither the UPSIT nor the CC-SIT have been packaged and sold specifically for the screening of possible Alzheimer's disease.

Numerous published scientific and medial studies have employed the UPSIT and the CC-SIT and a number have found smell loss to be among the first, if not the first, signs of Alzheimer's disease. In some cases these studies have demonstrated that such loss more or less predicts who, among at-risk individuals, will likely eventually develop AD.

The Early Alert™ Alzheimer's Home Screening Test is a smell test that allows an individual to determine if a loss of olfactory function is present. Although a lot all older persons with smell loss have AD, such loss, alone or in combination with memory problems and/or certain genetic markers, is among the best predictors or indicators of AD. Early Alert™ has been designed to assist in early detection of possible AD by determining if a person has a degraded sense of smell. Failing the test does not necessarily mean one has AD. If one fails the test, it is recommended that one sees his or her physician.

#### **Detailed Description of the Invention**

The test is a booklet approximately 3¼ by 6½ inches. The booklet is oriented for use in the "landscape" layout. The booklet has a front cover, an inside front cover, an inside back cover, an outside back cover and 12 individual inside pages.

The cover has the product name, Early Alert™ Alzheimer's Home Screening Test and two additional statements. The first is labeled IMPORTANT "Information booklet provided. Read the entire booklet prior to beginning the screening test. Follow the instructions carefully." The second is a marketing tagline "Have you ever wondered."

The inside front cover lists 8 very important facts and instructions in bullet form.

- Smell loss is among the first signs of Alzheimer's disease; this screening test measures your ability to smell.
- Do not attempt this screening test if you currently have nasal congestion or long lasting smell loss due to other known causes.
- Do not scratch the odor strip until you are ready to sniff the odor.
- Poor performance on this screening test does not necessarily mean you have Alzheimer's disease.
- This screening test works only if the directions are followed precisely as noted.
- This screening test can only be used one time and prior to the expiration date. Discard after use.

- Decreased olfactory function (sense of smell) is not the only indicator of potential Alzheimer's disease.
- Decreased olfactory function (sense of smell) can be found in older individuals without Alzheimer's disease.

Eleven of the inside pages have no printing on the back while the last page, the 12<sup>th</sup>, does have printing on the back. The pages all have the same format consisting of word and picture instructions on how to take the test. These instructions are printed on the left half of each page and repeated on all 12 pages.

The instructions are as follows:

1. Use pencil provided, scratch odor strip in ZIG-ZAG. (a small graphic is included)
2. Place odor strip directly under both nostrils and sniff. (a small graphic is included)
3. Circle best answer. You must circle one answer. (a small graphic is included)
4. Turn the page.

Each page is numbered, e.g. Odor #1, Odor #2, etc. On the right half of each page the question "This odor smells most like:" is repeated and is followed by a listing of four possible "names" for the odorant on that page. For example Odor #7 lists watermelon, peanut, rose and paint thinner as the possible odors. The correct answer is paint thinner. A note under the question "This odor smells most like:" requests that the user "Circle one".

The back of the page of Odor #12 has two printed sections. The first is "Scoring the Test" and the second is Reading the Results. The inside back cover faces the back of page Odor #12 and contains the Answer Key". This is a listing of all of the correct odors on each of the Odor pages. For example, Odor #1 is cinnamon; Odor #2 is turpentine, etc.

The test itself is 12 microencapsulated smell strips that are "scratched" to release an odor. A person sniffs the strip and chooses one of four possible answers shown on that page.

"Scoring the Test" instructs the user to look at the Answer Key. It then asks the user to compare each of his or her circled answers on each odor page to the Answer Key, instructing the user to "put a line through the answer if the selection and the answer do not match. Then after comparing all of the Odor pages to the Answer Key, the user is asked to total the number of odors that are incorrect or have a line through them and write that number in the box provided on the Answer Key page.

"Reading the Results" states "If you have 4 or more incorrect items you should consult your physician." It also suggests that if the user does not have 4 or more incorrect answers but is experiencing symptoms of AD, he or she should contact a physician. Additional caveats are printed here, such as "Early Alert™" is not a diagnostic test nor a conclusive test for Alzheimer's disease."

The outside back cover gives 6 storage and handling instructions, the Company name, phone number and the statement Patent Pending.

Claim 3 might be:

The test kit in Claim 2 wherein the scoring of the test is contained on a page at the end of the test book where the correct answers are given and a box is provided to enter the number of smells identified incorrectly.

The purpose in making the very, very broad Claim 1, is first to see if you can get the broadest possible claim allowed – "a possibility" says partner Robert Atkins. If the patent is rejected, and this is a good possibility, we immediately drop Claim 1 and proceed. I have used this tactic in previous patent applications and it works well.

Additional issues include:

1. We will need to compile all of the statistical information that states that 4 or more incorrect answers equate to failing the test. This would end up as a claim. Of course we need Dr. Doty's assistance with this.
2. We can immediately proceed with filing the patent in Canada and probably Japan. There are possible issues with the foreign patents in Europe due to our sales on the Internet. However, we will be filing a second patent to take care of that (see below).
3. We need to send a list of countries in which we want to file for foreign patents
4. Need dates for conference call with Dr. Doty after he sends the statistics
5. Additional retainer

It is our plan to immediately file a second patent with Davis, Doty, Feyrer-Melk and Gartner as the inventors, which will be an improvement or continuation in part of the first. It will likely add claims for a process wherein all of the pages of the booklets are printed at one time with a second press applying the "scented ink", thus eliminating the hand application of self-adhesive scented labels.

We might also add another claim to make the Answer Key or Scoring Page a fold out so the user does not have to flip back and forth to score the test.

The purpose in filing a second application is to clear the way for filing foreign patents in all desired countries. This will greatly strengthen our patent position.

We have the booklet marked as copyrighted. The attorneys suggest that we file a federal copyright on it for stronger protection.

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